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APPLICATION NO. 48 FILING DATE 5/97 BERG FIRST NAMED INVENTOR D ATTORNEY DOCKET NO.

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DUFFY EXAMINER

ART UNIT PAPER NUMBER

06/19/98

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Art Unit: 1645

DETAILED ACTION

1. The Group and/or Art Unit of U.S. Patent application S.N. 08/938,548 has changed. In order to expedite the correlation of papers with the application please direct all future correspondence to Technology Center 1600, Group 1640, Art Unit 1645.

Sequence Requirements

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

3. Applicant is given ONE MONTH, or THIRTY DAYS, whichever is longer, from the date of this letter within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a). Direct the response to the undersigned.

Applicant is requested to return a copy of the attached Notice to Comply with the response.

4. Full compliance with the sequence rules is required in response to this office action. A complete response to this office action should include both compliance with the sequence rules and a response to the election/restriction requirement set forth below. Failure to fully comply with **both** these requirements in the time period set forth in this office action will be held non-responsive.

Election/Restriction

5. Restriction to one of the following inventions is required under 35 U.S.C. 121:

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- I. Claims 1, 4, 13 and 14 drawn to polypeptide ligands for the HFGAN72 receptor, classified in class 530, subclass 350.
 - II. Claims 2 and 3, drawn to nucleic acids encoding the polypeptide ligands, classified in class 536, subclass 23.5.
 - III. Claim 5, 10 and 16, drawn to agonists and method of treatment using the agonists, classified in class 514, subclass 2.
 - IV. Claims 6 and 9, drawn to antibodies and methods of treatment using the antibodies, classified in class 530, subclass 387.1.
 - V. Claims 7, 8 and 15, drawn to antagonists and method of treatment using the antagonists, classified in class 514, subclass 2.
 - VI. Claim 11, drawn to methods of screening for agonists, classified in class 435, subclass 7.21.
 - VI. Claim 12, drawn to methods of screening for antagonists, classified in class 435, subclass 7.21.
6. The inventions are distinct, each from the other because of the following reasons:
- Inventions I, II, III, IV and V are related as products. In the instant case the products are chemically distinct: Group I - polypeptides, Group II - polynucleotides, Group III - agonists, Group IV - antibodies and Group V - antagonists. The products perform different biological functions: polypeptide ligand mediates a cellular biological function, polynucleotides encode the protein and antibodies specifically bind the ligand protein and mediate an immunological response. The antagonists and agonists are biologically and chemically distinct from the ligand because the antagonists prevents the biological activity of the ligand and thus is presumed structurally distinct. The agonist of the ligand, while function in a similar manner to the ligand is presumed

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chemically distinct. The products are produced by different methods. For example, the antibodies are produced by immunizing a host with the polypeptides where as the method of making the polypeptide involves transforming a host cell and isolating the heterologous polypeptide or isolating it by classical protein purification techniques. Antagonists or agonists are produced by chemical processes. Because the products have distinct chemical structures, perform different biological functions and are produced by different methods, the products are deemed distinct each from the other.

Inventions III , IV, V, VI and VII are related as methods. The methods are distinct each from the other because they have different goals and outcomes as evidenced by the preambles: Group III - method of treatment using the agonist, Group IV - method of treatment using the antibody, Group V - method of treatment using the antagonist, Group VI - method of screening for agonists and Group VII - methods of screening for antagonists, have different method steps: Group III - administering the agonists, Group IV - administering the antibody, Group V - administering the antagonist, Group VI - contacting cells expressing HFGAN72 with an agent suspected of activating the interaction of the receptor and ligand and Group VII - contacting cells expressing HFGAN72 with an agent suspected of inhibiting the interaction of the receptor and use different reagents: Group III - agonists, Group IV - antibodies, Group V - antagonists, Groups VI and VII - ligand and cells expressing HFGAN72 receptor polypeptides. For the foregoing reasons the methods are deemed distinct each form the other.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification, and in the absence of restriction would place an undue search and examination burden on the examiner, restriction for examination purposes as indicated is proper.

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Additionally, because these inventions are distinct for the reasons given above and the search required for Groups II, III, IV, V or VI are not required for Group I, restriction for examination purposes as indicated is proper.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

9. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1604 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy, Ph.D. whose telephone number is (703) 305-7555. The examiner can normally be reached on Monday-Friday from 6:30 AM to 3:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached at (703) 308-4310.

Patricia A. Duffy, Ph.D.
June 17, 1998

Patricia A. Duffy
Patricia A. Duffy, Ph.D.
Primary Examiner
Group 1640